IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	**Mail Stop Amendment**
Kenneth C. Cundy et al.	)	Group Art Unit: 1616
Application No.: 09/972,425	)	Examiner: BARBARA P. BADIO
Filed: October 5, 2001	)	Confirmation No.: 5701
For: BILE-ACID DERIVIED COMPOUNDS FOR PROVIDING SUSTAINED SYSTEMIC CONCENTRATIONS OF DRUGS AFTER ORAL ADMINISTRATION	)	

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In complete response to the Office Action of June 3, 2004, a Petition Under 37 C.F.R. § 1.136 (a) for one month being filed herewith extending the period for response from July 3, 2004, to August 3, 2004, Applicants submit the following response.

In the Office Action, the Examiner sets forth a restriction requirement among two hundred and twenty eight (228) groups of the claims. In addition, the Examiner requires Applicants to elect a single disclosed species from under the elected Group for search purposes.

Applicants respectfully traverse the restriction requirement as set forth in the Office Action.

Through the identification of these two hundred and twenty eight (228) groups of claims, groups 77 – 152 directed to compounds and compositions of formula I and groups 1 – 76 and 153 – 228 directed to methods utilizing compounds of formula I, the Examiner is requiring the dissection of Applicants' compounds of formula I into a vast number of generic subgroups, and the Examiner, rather than the Applicants, is identifying what Applicants regard as their invention (i.e., the compounds of formula

I and methods of using the compounds of formula I). As such, the Examiner is utilizing the restriction requirement to define what Applicants regard as their invention. Applicants respectfully submit that it is improper to use a restriction requirement, as the Examiner has done, to dissect the Markush groups of the compounds of formula I, as defined by Applicants. This dissection of Applicants' defined compound of formula I into a vast number of generic subgroups, as defined by the Examiner, constitutes a refusal on the part of the Office to examine the claim that Applicants believe to best represent their invention.

Applicants submit that it is improper for the Office to refuse to examine that which Applicants regard as their invention unless the subject matter of the claims lacks unity of invention. Specifically, in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978), the court articulated the general proposition that:

> [A]n applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Id. at 331. (Emphasis in original).

In view of the above and similar case law, the Patent Office has set forth a general policy regarding restriction of Markush-type claims in MPEP 803.02. According to the general policy as articulated in the MPEP, "since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334, it is ***improper*** for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984)." (MPEP 803.02, emphasis added). Unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature.

Applicants note that in order to expedite prosecution the claims were amended in the response filed on August 4, 2003. Applicants respectfully assert that the

presently claimed subject matter clearly exhibits unity of invention. With regard to a common utility, the compounds of the present claims use the bile acid transport system to provide sustained systemic concentration of orally delivered GABA analogs. With regard to a substantial structural feature, the compounds of the present claims all comprise a bile acid moiety linked to a GABA analog moiety. Applicants submit that the precise structure of the linker group connecting the bile acid moiety and the GABA analog moiety is not critical. According to the present invention, it is only necessary that the linking group be cleavable under physiological conditions to release the GABA analog moiety or active metabolite thereof into the systemic blood circulation. Therefore, Applicants respectfully submit that the compounds of the present claims clearly evidence unity of invention.

In view of the amended claims and the policy regarding restriction of Markush-type claims as provided above, Applicants submit that it is improper for the Office to refuse to examine the presently claimed invention since the presently claimed subject matter clearly evidences unity of invention.

Applicants note that a Petition from Requirement for Restriction was filed and in response, a Petition Decision issued granting Applicant's Petition. Applicants respectfully submit that the present Restriction Requirement is not in accordance with that Petition Decision, and Applicants respectfully request the Examiner to follow the Petition Decision. In this regard, Applicants note that the Petition Decision dated April 19, 2004, states that

> To some extent the examiner has done that by examining the elected species and determining that it is free of the prior art and has then expanded the search and examination of the species to a number of related species, also finding them free of the prior art. Where the examiner has erred is in then deciding that all applicants are entitled to is the species or subgeneric concept developed from the species by the examiner which has actually been examined. This is not in accord with In re Weber and other cases cited in M.P.E.P. 803.02. M.P.E.P. 803.02 requires the examiner after finding the elected species to be patentable to conduct an examination of a representative number of related species and ***then, if the examined species are also found to be free of the prior art to allow the entire genus***. This the examiner has not done.
>
> The examiner has indicated that method claim 1, if limited to the same scope as the compound claims, would also be considered allowable, but has as yet declined to allow such claims since claim 5 remains objected to. However, no formal restriction between method

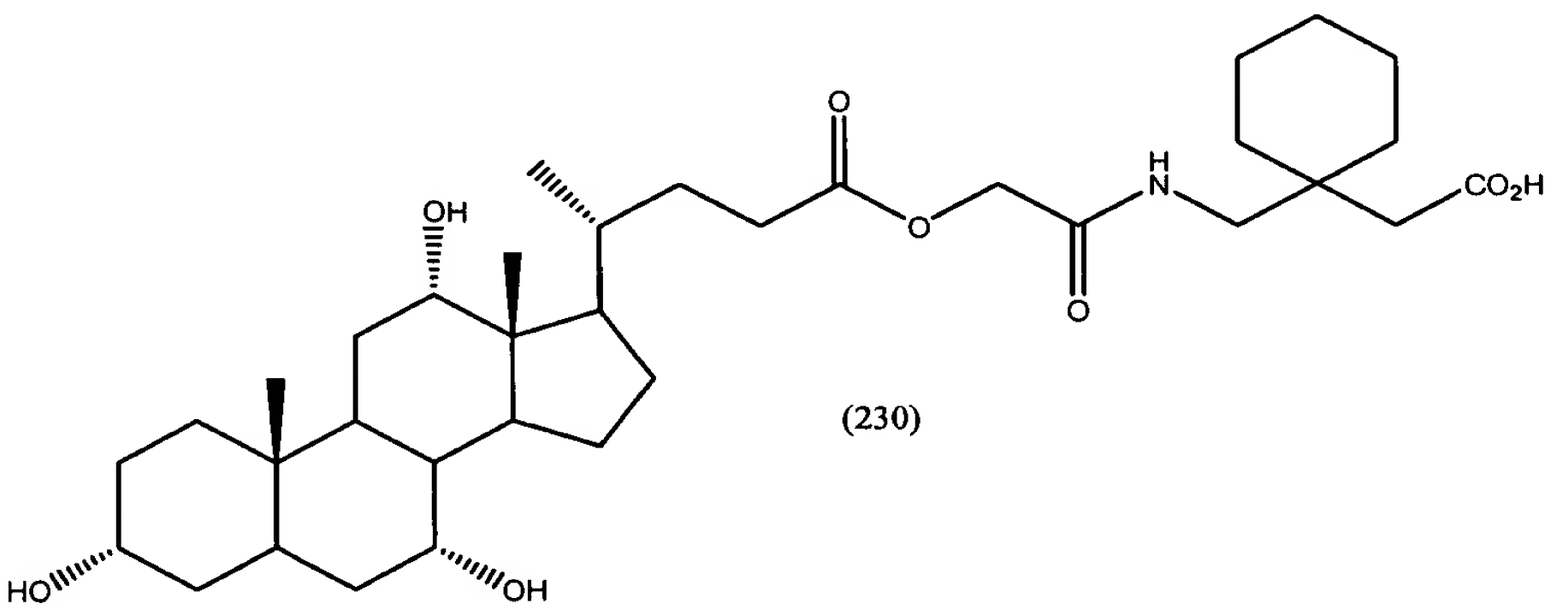
> and compound claims has been made and ***both types of claims must therefore be examined***.

Petition Decision, dated April 19, 2004, page 2, emphasis added.

As set forth above, Applicants respectfully traverse the restriction requirement as set forth in the Office Action. Thus, Applicants expressly reserve the right to Petition the Commissioner requesting removal thereof and requesting an action in accordance with the Petition Decision dated April 19, 2004.

Nevertheless, in order to comply with the requirements of 37 C.F.R. § 1.143, Applicants indicate below a provisional election of one group for examination and one species within the elected Group for purposes of searching. As such, Applicants elect, with traverse, Group 117, which includes claims 5, 6, 8-10, and 19, drawn to the compounds and compositions of formula I wherein Q^b is a linking group of formula $-[E-(F^*)_n-G]_m-$ and wherein E is –O-; F is selected from the group consisting of substituted or unsubstituted alkylene, substituted or unsubstituted alkenylene and substituted or unsubstituted alkynylene; G is –C(O) and wherein $R^{11'}$ is selected from the group consisting of carboxylic acid, carboxylic amide and carboxylic ester.

With regard to the species, Applicants elect, with traverse, compound 230, as shown below, for the purposes of searching only.



(230)

It is believed that claims 5, 6, 8-10, and 19 within the elected group (Group 117) are readable upon the elected species as defined above.

Applicants note that compound 230 was elected for the purposes of searching in the response filed on March 17, 2003 and Applicants further note that Group 117 is ***narrower*** than the generic group as defined by the Examiner and ***deemed allowable*** in

the Office Action dated May 2, 2003. In the Office Action dated May 2, 2003, the Examiner set forth the following generic group for examination:

> Compounds of Formula (I) wherein:
> (a) X is hydroxyl;
> (b) R^1 and R^2 are independently hydrogen or hydroxyl; and
> (c) Z is a group of the formula –M-Q^b-D' wherein
> M is selected from the group consisting of $-CH_2OC(O)-$ and $-CH_2CH_2C(O)-$;
> Q^b is $-[E-(F^*)_n-G]_m-$ and wherein E is –O-; F is defined by claim 8 (i.e., selected from the group consisting of alkylene, substituted alkylene, alkenylene, substituted alkenylene, alkynylene, substituted alkynylene, cycloalkylene, substituted cycloalkylene; cycloalkenylene, substituted cycloalkenylene, arylene, substituted arylene, heteroarylene, substituted heteroarylene, heterocyclene and substituted heterocyclene); and
> D' is a GABA analog moiety as defined by claim 5, wherein $R^{3'}$ is a bond linking the GABA analog moiety to Q^b and $R^{11'}$ is selected from the group consisting of carboxylic acid, carboxylic amide, and carboxylic ester.

Office Action dated May 2, 2003, page 2, paragraph 2.

In the Office Action dated May 2, 2003, the Examiner stated that "[c]laims 6-10 are objected to as containing nonelected inventions, but are allowable to the extent they read on the generic group defined above in paragraph #2. Note: Method claims 1-4 and 20 of the same scope as compounds of the generic group defined above in paragraph #2 would also be allowable." Office Action dated May 2, 2003, page 4, paragraph 6.

Applicants note that they traversed the Examiner's dissection of their invention into this "inventive group," as defined by the Examiner, and petitioned for withdrawal of the requirement. Applicants further note that their petition was granted as described above.

Conclusion

Applicants respectfully traverse the present restriction requirement which improperly dissects Applicants' compounds of formula I into a vast number of generic subgroups, as defined by the Examiner, with ***the elected group***, Group 117, ***being narrower*** than the ***generic subgroup previously indicated as allowable*** by the Examiner. As such, Applicants respectfully submit that it is improper to use a restriction requirement, as the Examiner has done, to dissect the Markush groups of the compounds of formula I, as defined by Applicants. Applicants respectfully submit

that as unity of invention exists in the presently claimed compounds, it is improper for the Office to refuse to examine the invention as claimed.

Applicants note that they have no intention of abandoning any non-elected subject matter and expressly reserve the right to file one or more continuation and/or divisional applications directed to the non-elected subject matter.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By _____
Melissa M. Hayworth
Registration No. 45,774

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Dated: August 3, 2004